SUPPORTING STATEMENT
FOR
REPORTING AND RECORDKEEPING REQUIREMENTS AND AVAILABILITY OF SAMPLE ELECTRONIC PRODUCTS FOR MANUFACTURERS AND DISTRIBUTORS OF ELECTRONIC PRODUCTS
OMB No. 0910-0025

1. Circumstances Making the Collection of Information Necessary

Sections 532 through 542 (21 U.S.C. 360ii through ss) (Attachment 1) of the Federal Food, Drug, and Cosmetic Act (the Act) direct the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program to protect the public from unnecessary radiation from electronic products. Section 532 of the act directs the Secretary to establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic radiation, and authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) directs the Secretary to review and evaluate industry testing programs on a continuing basis; and Sections 535(e) and (f) direct the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliances with performance standards. The authority for records and reports is contained in Sections in 537(b) – (c) of the Act. Such program shall include the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products.

The regulations promulgated under these authorities are listed in the Code of Federal Regulations (CFR), Title 21, Chapter I, Subchapter J. Specifically, 21 CFR parts 1002 - 1010 (Attachment 2) specify information to be provided to the Food and Drug Administration (FDA), to users, and/or to be maintained in the event of an investigation of a safety concern or a product recall. Subchapter A regulations, 21 CFR 5.10(a)(3), 5.25(b), 5.35(a)(1), and 5.86 through 5.92 (Attachment 3), delegate administrative authorities to the FDA and Radiological Health (CDRH).

The Center for Devices and Radiological Health (CDRH) also conducts laboratory compliance testing of products covered by regulations for product standards in 21 CFR Parts 1020, 1030, 1040, and 1050.

The FDA is requesting from the Office of Management and Budget (OMB) that approval be extended for the information collection requirements contained in 21 CFR Parts 1002, 1003, 1004, 1005, 1010, 1020, 1030, 1040, and 1050. (See Attachment 4)

Approval also is requested for the following forms:

FDA Form 2579	"Report of Assembly of a Diagnostic X-ray System"	(Attachment 5)
FDA Form 2767	"Notice of Availability of Sample Electronic Product"	(Attachment 6)
FDA Form 2877	"Declaration for Imported Electronic Products Subject To Radiation Control Standards"	(Attachment 7)
FDA Form 3147	"Application For A Variance From 21 CFR 1040.11(c) For A Laser Light Show, Display, or Device"	(Attachment 8)

This information collection is the consolidation of OMB Information Collections 0910-0025 "Reporting and Recordkeeping for Manufacturers and Distributors of Electronic Products, General Requirements", 0910-0048 "Notice of Availability of Sample Electronic Product", and 0910-0213 "Reporting and Recordkeeping for Electronic Product, Specific Product Requirements". Collections 0910-0048 and 0910-0213 will be retired upon OMB approval of this combined collection.

2. Purpose and Use of the Information

The information collections are either specifically called for in the Act or were developed to aid the Agency in performing its obligations under the Act. These requirements are placed upon manufacturers, importers, and assemblers of electronic products. The data reported to FDA and the records that are maintained allow FDA and the industry to make decisions and take actions, which protect the public from radiation hazards presented by electronic products. This information refers to the identification, location, operational characteristics, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

The reports are reviewed by FDA staff to determine product safety and adequacy of quality control testing. Potential and actual problems are resolved with the individual firm. The information supplied will be used by the FDA to locate and select sample products for conformance with regulations.

Forms were designed to aid respondents in the submission of this information. In the event this information was not collected by FDA on forms, each manufacturer would have to respond in letter format with all the data now on FDA forms, requiring more time and expense on their part. FDA would also then require written notification from Winchester Engineering and Analytical Center (WEAC), detailing all products received, from whom, returned to whom, model and chassis numbers, etc. to assure that the Agency's information coincided with their products. These extra steps to obtain information now on a form would significantly increase the cost in man-hours and duplications to both federal and industry organizations. Testing an appropriate percentage of these products to protect the public would also be hindered by any slower progress in FDA's receipt of the information.

The consequence of not obtaining the required information is that the public may unknowingly be exposed to unnecessary radiation hazards presented by electronic products. Without this information, FDA could not adequately make rational decisions and take appropriate actions to protect the public from these hazards as called for in the Act.

3. Use of Information Technology and Burden Reduction

The FDA is investigating several improved information technologies and methods to reduce the burden placed on manufacturers and assemblers, such as electronic transfer and optical storage of documents. The

FDA is also currently investigating the usefulness and appropriateness of a more expedient means of processing the data from the forms approved for this collection.

This collection's forms have been designed to provide the minimum needed information in order to process the testing of the product. Well-designed forms can eventually lead to creation of electronic submission systems for respondent use. The FDA is currently incorporating several other information technologies such as electronic transfer, fax and fax back systems, and the Internet to reduce the burden placed on manufacturers and importers.

FDA also has initiated a reengineering team, to investigate the use of electronic submission of data to allow easier reporting and reduced burden to this collection's respondents. The group is investigating the creation of an electronic submissions system that would be designed to automatically edit-check errors in submission to insure data integrity and provide trending and sampling analysis to FDA staff. The combination of this system with an internet world-wide web interface will reduce respondent burden in submission of data and FDA burden in review of this data. This team is also pursuing the creation of web-fillable PDF forms that will allow ease of user submission of radiological health data. A benefit of electronic submission systems is that the data requested by FDA is primarily a copy of information manufacturers generate in the normal course of business.

These methods will be incorporated when CDRH satisfies technical and legal requirements such as data integrity for a regulated industry and comparability of data.

The use of the FDA's optical scanning and retrieval system, IMAGE, is being tested for use in reviewing medical device submissions, such as Investigational Device Exemption (IDE) applications, and larger use of IMAGE in the radiological health area may be a future option.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only authorized Agency to control the radiation of electronic products. Therefore, these activities are not duplicated anywhere else. Those electronic products that are also medical devices may be subject to additional FDA regulations. In some cases there has been very little duplication of information and where there has been, exemptions have been granted so that the medical device reporting has precedence over electronic product reporting. Often, the documentation submitted to describe how radiation safety is assured through compliance with mandatory performance standards satisfies both medical device and electronic product reporting requirements simultaneously.

There is no other similar information collected that can be used to carry out the enforcement of these regulations.

5. Impact on Small Business or Other Small Entities

Protection of public health requires periodic testing of radiation emitting products. Small businesses are not exempt from this information collection's requirements, and regulations and testing are equally applied to

all firms, institutions, or individuals involved in conducting clinical investigations of non-medical products, regardless of the size of the organization. Efforts have been made to require the minimum amount of information possible for the Agency to make decisions and take actions to protect the public from radiation hazards presented by electronic products. Many of the FDA's recordkeeping requirements are part of normal records necessary for any business practice, and the disclosure information is typically included in the manuals that are provided with any manufactured product.

FDA has acted to minimize the burden to any firm whose product undergoes additional government testing by requiring the manufacturer or importer to ship tested products directly to WEAC in Winchester, Massachusetts. The government pays all shipping and insurance charges.

FDA currently maintains a fax on demand system (FACTS) which provides firms with information pertaining to medical devices and radiological health. FDA reengineering teams have also suggested creation of a web-based electronic data system for the submission of required information and a link to a generic electronic mail account on the website to provide assistance regarding questions and problems with Radiological Health and electronic products to all firms, regardless of size.

FDA also established the Division of Small Manufacturer's Assistance (DSMA), as required by the 1976 Amendments to the Act, to provide technical and other non-financial assistance to small firms, expressly to aid them in complying with the requirements of the Act. DSMA participates in and presents conferences, workshops, and seminars on the application and interpretation of relevant regulations. They also consult with individual firms/sponsors, and develop and disseminate educational materials. Staff is available to respond to questions and a toll free telephone number was established to facilitate this communication link. Additional information on DSMA may be obtained by and firm with internet access by logging onto the FDA's web site (http:\\www.fda.gov) and clicking on the Center for Devices and Radiological Health (CDRH) link.

6. Consequences of Collecting the Information Less Frequently

The frequency of the collection requirements depends on the device's date of introduction into commerce decided by the firm. In the event this information was not collected by FDA, each manufacturer would have to respond in letter format with all the data now collected on FDA forms, requiring more time and expense on their part. FDA would also require written notification from Winchester Engineering and Analytical Center (WEAC), detailing information such as all products received, from whom, returned to whom, model and chassis numbers, etc. to assure that FDA's information coincided with their products. These extra steps to obtain information now available on a form would significantly increase the cost in man-hours and duplications to both federal and industry organizations. If this information were obtained less frequently, fewer compliance tests could be completed, which could potentially result in endangering the public health through unnecessary exposure to electronic radiation. In the event that this product information was not provided to FDA in a timely manner, a hazard could go undetected and the risk to the public from unnecessary radiation would be increased significantly. If information was not provided to users, distributors, or assemblers at the time of possession of the product they may be unable to make rational decisions and take actions relating to safety. Because the initial product report required by 1040.10(a)(3)(i)

is only submitted once by each firm, the chance of public health risk increases as the length of time extends from the date of introduction of the device.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.

A few of the information collection requirements are inconsistent with that outlined in 5 CFR 1320.5 because immediate health hazards require immediate action and reporting should be prompt. If FDA and the affected industry or firm did not have access to this information, equipment could not be located quickly when a particular system is suspected of causing harm. If an entire model line is determined to be defective, the firm must be able to locate other installations of the defective units to eliminate additional hazards. For example, one of the collection requirements in this request is inconsistent with that outlined in 5 CFR 1320.5. Section 1020.30(d) requires the assembler of a diagnostic x-ray system to submit a report of assembly within two weeks of installation. This response time was agreed upon jointly by FDA and the manufacturers because it was felt that the two-week period was sufficient time to fill out and submit the Form FDA 2579 after completion of the assembly.

Over the past several years, recordkeeping requirements have been significantly reduced, but the timeframe for maintaining these records (5 years) remains the same. These records are needed for significant risk products, and therefore are considered records pertaining to health which are not subject to the 3 year limit [5 CFR 1320.5(f)].

If FDA did not possess this information, equipment could not be located quickly when a particular system is suspected of causing harm, and the protection of the public from significant health risks might be compromised.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

Notice has been published in the Federal Register on June 5, 2000 (65 FR 35648) soliciting comments on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d) (see Attachment 9). The following is a summary of the comments and the agency=s responses to them.

One comment asked for elimination of reporting requirements and enforcement of field surveillance. The comment stated that current reporting requirements are excessive and unnecessary and not in line with international trend. It was suggested that a ASupplier=s Declaration of Conformity≅ to the emission standards would be sufficient. Manufacturers and importers could provide FDA with information required in the current reporting requirements upon request.

FDA was not persuaded by this comment. Reports and field surveillance are needed to ensure that product complies with federal performance standards. FDA is in the process of re-engineering the Radiological Health Program and is looking into ways of trying to help alleviate some of the burden. FDA is currently reviewing its reporting requirements and is considering exemption from reporting for certain products and electronic filing for others. The comment will be taken into consideration.

One comment requested that Class I laser products containing Class I lasers should be excluded from the reporting requirements and a declaration be added to the import form FDA 2877 stating that the products are compliant products. This would eliminate the need for an accession number.

FDA partially agrees with this suggestion and has already exempted manufacturers who have previously submitted reports from reporting new Class I products (those to which access to laser radiation in excess of Class I during operation, maintenance, service, and single failure has been limited). At this time, there is no way to distinguish these types of Class I products from other Class I products through either tariff codes or database product codes. FDA is considering different options to help alleviate the problem other than adding a new declaration to the form. During the re-engineering process, FDA will take into account the suggestion.

One comment stated that FDA=s import requirements are outdated and most of the information requested for every entry is redundant. FDA can simplify the import clearance process by limiting data fields and cross-referencing databases. Also, the import form FDA 2877 does not take into account multiple regulated products that can be included on an entry.

FDA disagrees with the comment that import requirements are outdated and most of the information requested for entries is redundant. Some data elements on the FDA 2877 are required by Customs and also assist FDA in limiting the scope of import detentions or import review. For example, some countries may have a problem while other countries do not, or some product types may have a higher surveillance rate due to a non-compliance problem. By obtaining such data FDA can better target those shipments that need to be detained for investigation and thus permit more shipments to proceed unhindered.

FDA agrees that the process can be simplified but cannot cross-reference data between databases at this time because databases are very different. Budget allocation and several years= effort will be required to update the databases.

FDA agrees that the import form FDA 2877 does not take into account multiple regulated products that are included on an entry. If the information does not fit in the box provided on the form a list may be attached.

One comment stated that the name and address of manufacturing site and country of origin creates confidentiality concerns for the manufacturer of record.

FDA was not persuaded by this comment. While FDA appreciates the unique situation to manufacturers this information is required by Customs and assists FDA in targeting certain areas where there is a need to monitor certain products. FDA will continue to explore methods to reduce informational requirements while maintaining FDA=s ability to detain and refuse violative products.

One comment recommended that a new declaration be added to the FDA form 2877 reflecting the May 14, 1997, notice to industry regarding importation of non-compliant products intended for testing and evaluation during the design and development stage instead of the importer having to use Declaration C.

FDA disagrees with this comment. Currently there is a declaration (A6) that takes into account the notice. The notice is intended for certain types of non-compliant products. Declaration C should be used for products that are not listed in that notice.

Three comments proposed electronic filing of radiation reports to minimize the burden of the collection of information and enhance the quality, utility and clarity of information to be collected.

FDA agrees with this comment and is currently working on this process. FDA must accept electronic submissions by September 2003.

FDA staff met with the Stakeholders on Radiological Health Reengineering on January 26, 2000. General concepts of improvements in the agency program and alternatives to reporting were discussed. Industry and trade association attendees included:

Larry Kroger
GE Medical Systems
(representing National Electrical Manufacturers Association)
3000 N. Grandview
W-709
Waukesha, WI 53188
262-544-3894

Michelle Gutberlet
Electrical Energy Association
1255 23rd Street NW
Suite 200
Washington, DC 20037
202-452-1070

The FDA/CDRH's Office of Compliance staff met with the R-1 Safety Committee of the Consumer Electronics Manufacturers Association (now Consumer Electronics Association) on August 24, 1999. Reporting and recordkeeping burdens were discussed, among other topics. Industry representatives included:

Neal Hursh
Thomson Consumer Electronics
600 North Sherman Drive
Indianapolis, IN 46201-2598
317-267-5203

Ramon Cabrera
Matsushita Electric Corporation of America
One Panasonic Way
Secaucus, NJ 07094
210-348-7759

Richard Long
Sharp Electronics Corporation
Sharp Plaza
Mahwah, NJ 07430-2135
210-529-9689

FDA routinely consults with members of industry, government, and the public through the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and the Radiological Devices Panel (RDP). These committees are permanent advisory committees established under Sections 534(f) and 513(b) of the Act. FDA is required to consult with the TEPRSSC before establishment of or changes to standards, and the RDP advises FDA on use of radiation in the healing arts. FDA met with the TEPRSSC group in June, 2000.

FDA's Radiological Health Recordkeeping and Reporting reengineering team examined if Radiological Health reporting requirements could be improved to reduce both respondent and government burden. The team began meeting in January, 2000, and a possible outcome could be a change in regulations to reduce respondent burden. The team's final recommendations are due to Center management in September, 2000.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift provided to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondent

Section 537 of the Act states that the Secretary shall not disclose any information which contains or relates to a trade secret or other matter referred to in Section 1905 of Title 18 of the United States Code. Information provided under this collection is handled in a manner to comply with this requirement and the FDA regulations implementing the Freedom of Information Act, 21 CFR Part 20. All information provided will be protected from inappropriate disclosure.

11. Justification for Sensitive Questions.

The information required does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

The most likely respondents to this information collection will be electronic product and x-ray manufacturers, importers, and assemblers.

The total estimated reporting and recordkeeping burden for this information collection is 324,957 hours.

FDA estimates the burden of this collection of information as follows:

Estimated Annual Reporting Burden

21 CFR Section	Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1002.3		10	1	10	12	120
1002.10 and 1010.3		540	1.6	850	24	20,400
1002.11		1,000	1.5	1,500	0.5	750
1002.12		150	1	150	5	750
1002.13 Annual		900	1	900	26	23,400
1002.13 Qtrly		250	2.4	600	0.5	300
1002.20		40	1	40	2	80
1002.50(a) and 1002.51		10	1.5	15	1	15
	FDA 2877	600	32	19,200	0.2	3,840
1010.2		1	1	1	5	5
1010.4 (b)		1	1	1	120	120
1010.5 and 1010.13		3	1	3	22	66
	FDA 2767	145	11.03	1,600	0.09	144
1020.20 (c)(4)		1	1	1	1	1
1020.30(d), (d)(1), and (d)(2)	FDA 2579	2,345	8.96	21,000	0.30	6,300
1020.30 (g)		200	1.33	265	35	9,275
1020.30 (h)(1) through (h)(4), 1020.32 (a)(1) and (g)		200	1.33	265	35	9,275
1020.32(g) and 1020.33(c);(d); (g)(4); (j)(1) and (j)(2)		9	1.00	9	40	360
1020.40(c)(9)(i) and (c)(9)(ii)		8	1.00	8	40	320
1030.10(c)(4)		41	1.61	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)		41	1.61	66	20	1,320
1030.10(c)(6)(iii) and (c)(6)(iv)		1	1	1	1	1
1040.10(a)(3)(i)		83	1	83	3	249

1040.10(h)(1)(i) through (h)(1)(vi)		805	1.00	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)		100	1.00	100	8	800
1040.11(a)(2)		190	1.00	190	10	1,900
1040.11(c)	FDA 3147	53	2.2	115	0.5	58
1040.20 (d), (e)(1), and (e)(2)		110	1.00	110	10	1,100
1040.30(c)(1)		1	1.00	1	1	1
1040.30(c)(2)		7	1.00	7	1	7
1050.10(f)(1) through (f)(2)(iii)		10	1.00	10	56	560
TOTAL ANNUAL REPORTING BURDEN						89,278

(Footnote) There are no capital costs or operating and maintenance costs associated with this collection.

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1020.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals					235,679

(Footnote) There are no capital costs or operating and maintenance costs associated with this collection.

The burden estimates were derived by consultation with FDA and industry personnel. FDA's estimates are based on actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals.

The estimated respondent reporting burden is 89,278 hours. This burden affects 4,100 firms, requiring an average of 21.8 hours per firm annually. The estimated recordkeeping burden is 235,679 hours. This burden affects 4,100 firms, and requires an average of 57.4 hours per firm annually. Since most of the burden is in generating rather than maintaining records, FDA reduced the number of records rather than the maintenance time in their estimates. The remaining records are not considered to be subject to the 3 year limit (5 CFR 1320.6(f)) since they are part of the health risk assessment records for significant risk products.

The estimated annual cost to the industry is $7,961,447, based on hourly burden presented in the burden charts. This amount is derived from the total burden hours (324,957 hours) multiplied by an average estimated industry cost of $24.50 per hour ($51,000 per staff year of 2080 hours). The average hourly cost includes overhead, technical staff, support staff, etc., and was based on the Regulatory Affairs Professional Society (RAPS) "1995 Salary Survey Final Report". Using the RAPS Salary Survey, FDA estimates that the average cost for respondents to prepare and submit records and reports is $24.50 per hour.

The following information collection requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (I); 1004.3(a) through (I); 1004.4(a) through (h); and 1005.21(a) through (c). These requirements apply to the collection of information during the conduct of general investigations or audits (5 CFR 1320.4(b)). The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

There are no capital or operating/maintenance costs associated with this regulation.

14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal government is $2,024,100. During the last CDRH "Center Automated Time Reporting Survey" in November 1999, CDRH estimated that 20 Center employees participated in activities under the Radiological Control for Health and Safety Act. The estimated cost was determined by computing the total fully loaded (i.e. with benefits, etc.) full time equivalent (FTE) cost. This cost was determined by taking the 20 staff positions and multiplying by the fully loaded cost of $89,705 per staff year of 2,080 hours. The total cost of $1,794,100 was then increased by the $230,000 contract for data/document management, bringing the total cost to $2,024,100.

15. Explanation for Program Changes or Adjustments

The burden represented by this collection has increased by 39,468 hours from the original 0910-0025 information collection burden hours of 285,489 because this collection is the result of the consolidation of OMB Information Collections 0910-0025, 0910-0048, and 0910-0213. OMB Collections 0910-0048 and 0910-0213 will be retired upon approval of this collection, and their burden will be removed from CDRH's hourly inventory upon their retirement.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the collection of information under these regulations for statistical use unless requested by Congress in accordance with Section 533 of the Act.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions. There are no exceptions to the certification statement identified in Item 19 of the OMB Form 83-I.

B. Collection of Information Employing Statistical Methods.

Information submitted which is found susceptible to tabulation for statistical purposes may be tabulated in accordance with program needs, however, there are no statistical methods being employed in this collection of information.

List of Attachments to Supporting Statement

Attachment 1 - The Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C (former title: The Radiation Control for Health and Safety Act of 1968 (P.L. 90-602))
Attachment 2 - Electronic Product Radiation Control Regulations (21 CFR Chapter I, Subchapter J, parts 1002-1010, 1020, 1030, 1040, and 1050)
Attachment 3 - Delegation of Authority Regulations (21 CFR Chapter I, Subchapter A, part 5)
Attachment 4 - 21 CFR 1002 to 1050 Information Requirements
Attachment 5 - FDA Form 2579 “Report of Assembly of a Diagnostic X-Ray System”
Attachment 6 Form FDA 2767, "Notice of Availability of Sample Electronic Product"
Attachment 7 - Form FDA 2877 and instructions
Attachment 8 - Form FDA 3147 and instructions
Attachment 9 - Federal Register 60 Day notice June 5, 2000 (65 FR 35648).

Attachment 4

21 CFR 1002 – 1050 Information Requirements

FDA is requesting approval from the Office of Management and Budget (OMB) for the information collection requirements contained in 21 CFR Parts 1002, 1003, 1004, 1005, 1010 1020, 1030, 1040, and 1050 as follows:

21 CFR 1002.3 - Disclosure - Notification:
Requires manufacturers, when directed by the FDA, to provide technical and safety information to users.

21 CFR 1002.10(a)-(k) - Reporting:
Requires manufacturers to report to FDA product identification, product design and operation, product testing, quality control procedures, test results, and product labeling prior to the entry of the product into commerce.

21 CFR 1002.11(a)-(b) - Reporting:
Requires manufacturers to provide information to FDA on changes in product safety or testing.

21 CFR 1002.12(a)-(e) - Reporting:
Requires manufacturers to report abbreviated information on product safety and testing, instead of 1002.10 reports.

21 CFR 1002.13(a)-(c) - Reporting:
Requires manufacturers to report annually to FDA a summary of manufacturer records maintained in accordance with 1002.30, and provide quarterly updates of models instead of 1002.10 or .11 reports.

21 CFR 1002.20(a)-(c) - Reporting:
Requires manufacturers to report to FDA the circumstances, amount of exposure, and remedial actions taken concerning any accidental radiation occurrence involving their electronic products. If a firm is also required to report the incident under 21 CFR 803, those regulations take precedence.

21 CFR 1002.30(a)-(b) - Recordkeeping:
Requires manufacturers to keep records on test data and procedures, correspondence regarding radiation safety, and distribution records.

21 CFR 1002.31(c) - Reporting:
Requires manufacturers, when requested by FDA, to provide copies of the distribution records required to be maintained by 1002.30(b). [Excluded under 5 CFR 1320.3(c).]

21 CFR 1002.40(a)-(c) - Recordkeeping:
Requires dealers and distributors to retain first purchaser information, to be used by manufacturers when a product recall is instituted to insure the radiation safety of a product.

21 CFR 1002.41(a)-(b) - Recordkeeping:
Specifies that the dealer/distributor records in 1002.40 may be retained by the dealer or forwarded to the manufacturer for retention; also that the manufacturer or dealer shall retain distribution records (1002.30(b) and 1002.40) for five years. The burden is included in those sections.

21 CFR 1002.50(a) - Reporting:
Specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements when there is a low risk of injury.

21 CFR 1002.51 - Reporting:
Specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements if the product is intended for U.S. Government use. The burden is combined with the 1002.50 exemption request, because the processes are essentially identical.

21 CFR 1003.10(a)&(c) - Reporting:
Requires manufacturers to notify FDA when their product has a defect or fails to comply with applicable performance standards. If 21 CFR 803 also applies, that regulation takes precedence. [Excluded under 5 CFR 1320.3(c).]
21 CFR 1003.10(b) - Disclosure - Notification:
Requires manufacturers to notify purchasers, dealers, and distributors of product defects or noncompliances, including a description of hazard, instructions for use pending correction, and a corrective action plan. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.11(a)(3) - Reporting:
Specifies criteria by which manufacturers may refute FDA's notice of defective or noncompliant product. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.11(b) - Reporting:
Requires manufacturers, when notified by FDA, to provide information on the number of defective products introduced into commerce. Firms provide the information with the 1003.10(a) report. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.20(a)-(h) - Reporting:
Requires manufacturers to provide to FDA the same report as 1003.10(a), under different circumstances of discovery. [Excluded under 5 CFR 1320.3(c).]

12 CFR 1003.21(a)-(d) - Disclosure - Notification:
Specifies the content of the notification required by 1003.10(b). [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.22(a)-(b) - Reporting:
Requires manufacturers to provide to FDA copies of the 1003.10 disclosure sent to purchasers, dealers or distributors. Firms provide the information with the 1003.10(a) report. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.30(a)-(b) - Reporting:
Specifies criteria by which manufacturers may request an exemption from the 1003.10 disclosure and possible product recall. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1003.31(a)-(b) - Reporting:
Specifies the content of the 1003.30 report. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1004.2(a)-(i),
21 CFR 1004.3(a)-(i),
or 21 CFR 1004.4(a)-(h) - Reporting:
Requires manufacturers to report to FDA a plan to remedy a product defect or noncompliance through repair or replacement or refund. [Excluded under 5 CFR 1320.3(c).]

21 CFR 1005.21(a)-(c) - Reporting:
Specifies criteria for manufacturers or importers to request correction of noncompliant products for importation into the United States, including specific corrections, timeframe and location for completion. Such requests are made on Form FDA 766, Application for Authorization to Relabel or to perform other action of the Federal Food, Drug, and Cosmetic Act and other related Acts. [Excluded under 5 CFR 1320.3(c), (*Attachment 8*).]

21 CFR 1005.25(a)-(b) - Reporting:
Requires importers to report identification information and compliance status of products to FDA. Initial designations are provided in the 1002.10, 1002.11, and 1002.12 reports, so that burden is included in those sections. For each shipment, identification is made on Form 2877.

> **Form FDA 2877**, Declaration for Products Subject to Radiation Control Standards (*Attachment 6*) is used to collect this information. This form will be amended in the future to clarify a number of concerns expressed by both importers and FDA imports offices. It will be sent to OMB for clearance when it is ready. We do not anticipate any change in burden. Approval of the current form is requested.

21 CFR 1010.2(d) - Reporting:
Specifies criteria for manufacturers to request alternate means of certification to a standard.

21 CFR 1010.3(a)-(c) - Reporting:
Requires manufacturers to provide to FDA the coding systems if information on labels is coded and to identify each brand name, and the name and address of the individual or company for whom each product so branded is manufactured. Firms provide such information in the 1002.10, 1002.11, and 1002.12 reports, therefore the burden is included in those sections.

21 CFR 1010.4(b) - Reporting:
Specifies criteria for manufacturers to petition FDA for a variance from a performance standard including

alternate means of safety, or suitable means of safety along with reasons why the standard is inappropriate.

Form FDA 3147, Application for a Variance from 1040.11(c) for a Laser Light Shows (*Attachment 7*) is used only by manufacturers of laser products to submit the required information. Since the vast majority of variances are submitted by this industry this form was developed to reduce the burden and timeframe for approvals. (No form is applicable to other products.) There is no change to the form. Approval of the form is requested.

21 CFR 1010.5(c)-(d) - Reporting:
Specifies criteria by which manufacturers or U.S. government agencies may request an exemption (or amendment or extension) from performance standards when a product is to be used exclusively by a part of the U.S. Government and has adequate radiation emission specifications.

21 CFR 1010.13 - Reporting:
Specifies criteria for manufacturers to request alternate test procedures from those specified in a performance standard. The burden is combined with 1010.5(c)-(d) because the processes are essentially identical.

1020.20(c) (4) - Disclosure - Notification (Reporting):
Requires manufacturers of cold cathode tubes to provide safety instructions and specifications to users.

1020.30(d) (1)&(2) - Reporting:
Requires individuals or companies who install certified diagnostic x-ray components to submit a report of assembly to FDA as certification that the final product meets safety regulations (Form FDA 2579*). Section 21 CFR 1020.30(d)(2) of the regulation was amended to omit some requirements which had resulted in a burden reduction. In this section, reports of assembly need not be submitted for replacement tube housing assemblies that are reinstalled in or newly assembled into existing x-ray systems; Certified accessory components under 21 CFR 1002.10; repaired components; or temporarily installed components into an x-ray system.

*** Form FDA 2579**, Report of Assembly of a Diagnostic X-ray System, is used to obtain the required information requested in 21 CFR 1020.30(d); therefore, FDA is also asking for reinstatement of approval of the form. There are no changes to the form since its last approval by OMB.

1020.30(g) - Disclosure - Notification (Reporting):
Requires manufacturers of diagnostic x-ray systems and their major components to provide assembly, installation, compatibility, and testing information to assemblers of such products, and others upon request.

1020.30(g) (2) (Recordkeeping):
Requires manufacturers of diagnostic x-ray systems and their major components to provide assemblers a statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator.

1020.30(h) (1)-(4) - Disclosure - Notification (Reporting):
Requires manufacturers of diagnostic x-ray systems and their major components to provide safety and technical information and instructions to the purchasers and users of such products, and others upon request.

1020.32 (a) (1) Disclosure - Notification (Reporting):
Requires manufacturers of fluoroscopic x-ray equipment to provide precautions and safety information to users. It is provided in the same manual as the information required in 1020.30(g).

1020.32 (g) Disclosure - Notification (Reporting):
Requires manufacturers of radiographic systems that contain Positive Beam Limitation (PBL) to provide precautions and safety information to users. It is provided in the same manual as the information required in 1020.30(g).

1020.33(c) - Disclosure - Notification (Reporting):
Requires manufacturers of Computed Tomography (CT) x-ray systems to provide technical and safety information to users. It is provided in the same manual as the information required in 1020.30(h), or in a separate manual devoted entirely to this information.

1020.33(d) - Disclosure - Notification (Reporting):
Requires manufacturers of CT systems to provide quality assurance information to users. It is provided in a separate section in the same manual as the information required in 1020.30(h).

1020.33(g) (4) - Disclosure - Notification (Reporting):
Requires manufacturers of certain CT systems to provide alignment instructions to users. It is provided in the same manual as the information required in 1020.30(h).

1020.33(j) (1)&(2) - Disclosure - Notification (Reporting):
Requires manufacturers of CT x-ray systems to provide specific, technical instructions concerning the use of the method provided for calculation of the CT number mean and standard deviation to users. The information provided according to 21 CFR 1020.30(h) should be in the same manual as the information required in 1020.30(h).

1020.40(c) (9) (i)&(ii) - Disclosure - Notification (Reporting):
Requires manufacturers of cabinet x-ray systems to provide technical, safety, maintenance, and assembly information to purchasers.

1030.10(c) (4) Disclosure - Notification (Reporting):
Requires manufacturers of microwave ovens to provide legible radiation safety instructions to users. This information should be contained in a separate section and should be an integral part of requirements supplied in an enclosed cookbook or users manual.

1030.10(c) (5) (i-iv) - Disclosure - Notification (Reporting):

Requires manufacturers of microwave ovens to provide safety information and adequate instructions to service dealers and distributors and others upon request.

1030.10(c) (6) (iii) - (Reporting):
Describes warning labels on Microwave Ovens. In the history of this performance standard, the Director for the Center for Devices and Radiological Health has never determined that a specific warning is required for a microwave oven manufacturer. Therefore, this citation has been added to the burden chart with a minimal burden.

1030.10(c) (6) (iv) - (Reporting):
Specifies the information to be provided to FDA when a manufacturer of microwave ovens requests an exemption from required user warning labels.

1040.10 (a) (3) (i) (Reporting):
Requires manufacturers of laser products sold for use as a component or replacement to register with FDA and provide a listing by type of product in lieu of the reporting required by 1002.10 (0MB 0910-0025).

1040.10 (a) (3) (ii) - (Recordkeeping):
Requires manufacturers of laser products sold for use as a component or replacement to maintain distribution records in accordance with 1002.31 (0MB 0910-0025).

1040.10(h) (1) (i)-(vi) - Disclosure - Notification (Reporting):
Requires manufacturers of laser products to provide assembly, operation and maintenance instructions, technical information, legible reproductions of all label and hazard warnings, and a listing of all controls, adjustments, and procedures for operations and maintenance to users- The FDA is considering an amendment to simplify the information and harmonize with the international standards.

1040.10(h) (2) (i)-(ii) - Disclosure - Notification (Reporting):
Requires manufacturers of laser products to provide service information to dealers and distributors and to others upon request. It is provided in the same manual, as information required in 1040.10(h)(1).

1040.10(i) - (Reporting):
Requires manufacturers of laser products to recertify and reidentify the product in accordance with 1010.2 and 1010.3. Thus, the firm is required to report compliance information to FDA as required by 1002.10 (burden documented in 0MB 0910-0025).

1040.11 (a) (2) - Disclosure - Notification (Reporting):
Requires manufacturers of certain medical laser products to provide instructions and a schedule for calibration with each product. It is provided in the same manual, as information required in 1040.11(A)(1).

1040.20 (d) & (e) (1)&(2) - Disclosure - Notification (Reporting):
Requires manufacturers of sunlamps or ultraviolet lamps to provide warning labels, use instructions, and technical and safety information to users.

l040.30 (c) (1) - Disclosure - Notification (Reporting):
Describes the general regulations for high intensity, mercury vapor discharge lamps, specifically the labeling of these lamps. Burden in this area is considered negligible, as the imprinting of the lamps has become industry standard. Industry also has said that if this requirement were eliminated, they would continue the practice because of the cost implications of retooling all manufacturing of mercury vapor lamps.

l040.30 (c) (2) - Disclosure - Notification (Recordkeeping):
Describes labeling of mercury vapor discharge lamps in lieu of permanently affixing or inscribing tabs or labels on the product as required by §§ 1010.2(b) and 1010.3(a). The manufacturer of any high intensity mercury vapor discharge lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the applicable lamp.

1050.10(f) (1) - Disclosure - Notification (Reporting):
Requires manufacturers of ultrasonic therapy products to provide service information to dealers and distributors and others upon request. Also provides user instructions concerning safety and precaution, adequate description of the spatial distance of the ultrasonic radiation field, and adequate description of the uncertainties of magnitude.

1050.10(f) (2) (i)-(iii) Disclosure - Notification (Reporting):
Requires manufacturers of ultrasonic therapy products to provide safety and technical information to users. It is provided in the same manual as information required in 1050.10(f) (1).